

Institutional Review Board (IRB Form 106)

Annual and Closeout Report Form

NSU Researcher Information

Principal Investigator _____

Select One:

Faculty ☐

Staff ☐

Student ☐

School/Unit _____

Department/
Center _____

Phone # _____

Email _____

Campus Address _____

External Investigator Information

Principal Investigator _____

Select One:

Faculty ☐

Staff ☐

Student ☐

School/Unit _____

Department/
Center _____

Phone # _____

Email _____

Campus Address _____

1. Project Information

Title _____

Brief Description

Attach an additional sheet if necessary.

Funding Agency _____

Do you wish to continue this
research?

Yes ☐

Post the current consent form to this project in IRBNet.

No ☐

This will be considered the closeout report for the project (not for
closure to patient entry).

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II. Report Data

1. Report Period _____ to _____
MM/DD/YY (up to 1 year)

2. Is this research project ongoing at this site? Yes ☐ No ☐ Termination Date: _____

3. Did you actively enroll subjects or collect data during the report period? Yes ☐ No ☐

4. Please provide the following information for this site:

Required Information	Totals for the Report Period
Number of Subjects Enrolled	
Number of Subjects Enrolled by Category (federal government reporting requirement)	
Males	
Females	
Black, Non-Hispanic	
American Indian/Alaskan Native	
Asian/Pacific Islander	
Hispanic	
White, Non-Hispanic	
Other or Unknown	
Number of Subjects Withdrawn from the Study	

Required Information	Totals
Total Number of Subjects Enrolled Since the Initiation of This Project	
Number of Subjects Engaged in the Study at the Present Time	
Number of Subjects Withdrawn from the Study Since Initiation	

5. Total Number of Subjects Enrolled Across All Sites to Date _____

6. Is the study closed to subject entry? Yes ☐ No ☐

7. If yes, date of closure (day/month/year): _____

8. Is closure permanent? Information Yes ☐ No ☐

9. If your study provided incentives to the participant(s), please fill out the incentive distribution information below. Add additional information on separate sheet if needed.

Date	Pseudo ID	Type (Cash, Gift Cards, or Merchandise) All gift cards must have gift card numbers listed.	Amount	How it was given? (In person, electronically, mailed, etc.)

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10. Please describe any medical, legal or practical difficulties that were encountered during the reporting period of the study aside from adverse events. Difficulties may include complaints of subjects, logistic problems of performance, or any difficulties that may pertain to the rights of these subjects.

Attach an additional sheet if necessary.

11. Number of local adverse events:

11. Number of non-local adverse events:

12. Please provide a brief description of trends in adverse events. Adverse events must be reported to the NSU IRB within five days of the investigator being notified. If there are events that have not been reported to the IRB, submit notification with a brief explanation via IRBNet.

Attach an additional sheet if necessary.

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	Response	
	Yes	No
13. Has the protocol or consent form changed in any way since the last approval? If yes, use IRBNet to submit to a copy of any amendment(s) not previously submitted.	<input type="checkbox"/>	<input type="checkbox"/>
14. Has any new information become available during the course of the research that may affect the subject's willingness to continue participation in the study?	<input type="checkbox"/>	<input type="checkbox"/>

If yes, explain:

	Response	
	Yes	No
15. Was new information provided to subjects? If yes, use IRBNet to submit documentation.	<input type="checkbox"/>	<input type="checkbox"/>
16. Is there recent information, especially regarding risks associated with the research, that the IRB should be aware of when conducting the continuing review? If yes, use IRBNet to submit the pertinent information.	<input type="checkbox"/>	<input type="checkbox"/>

Please use IRBNet to submit a brief overview of research results/observations obtained to date. If applicable, include local and multisite information and one copy of any publications that have resulted from this research.

NSU Principal Investigator/NSU Representative Name and Signature Date

External Investigator Name and Signature (if applicable) Date

NSU Department Head/Dean Print Name and Signature Date